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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/409,792	09/30/1999	MARTIN P. FOLEY	6298/308	5860
757	7590	10/06/2004	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			LEWIS, AARON J	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 10/06/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/409,792

Applicant(s)

FOLEY ET AL.

Examiner

AARON J. LEWIS

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06/29/2004 (AMENDMENT).  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-52 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 31-52 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31-33,36,38,40,41 are rejected under 35 U.S.C. 102(b) as being anticipated by Braecklein ('010).

As to claim 31, Braecklein discloses a mask for inhalation of medication (page 2, lines 11-13) comprising: a front portion having an inlet (13) adapted for connection to a source (20) for providing an aerosol medication (page 2, lines 11-13), wherein said mask has minimal dead space inside (fig.1) yet provides efficient inhalation and exhalation flow paths that purge said mask of exhaled air; a side wall expanding outwardly from said front portion to a rear portion (see portion which engages a wearer's face in figs.1 and 2) adapted to fit sealingly (page 1, lines 66-68) on a human face; a wall located adjacent said front portion, and an integrally molded valve (17) formed in an opening in said wall, said integrally molded valve adapted for positioning adjacent said nostrils of a nose; and wherein said integrally molded valve is adapted to permit air flow through said opening upon a patient breathing in a first direction, and to prevent air flow through said opening upon the patient breathing in a second direction opposite the first direction.

As to the recited "integrally molded" manner of making the claimed mask, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. While the mask and exhalation valve of Braecklein may have been made by a different process, it does include the claimed elements of the mask as defined in claim 31 and therefore, anticipates the mask of claim 31.

As to claim 32, Braecklein discloses the integrally molded valve to comprise an exhalation valve (17).

As to claims 33,38, Braecklein (fig.1) illustrates exhalation valve (17) to be in fluid communication with a tunnel-like extension projecting from said side wall.

As to claim 36, Braecklein (fig.1) discloses a mask for use with an aerosol delivery device, the mask comprising: an inlet (13) for receiving an end of a medication aerosol delivery device (20), said inlet adapted for substantial alignment with a mouth of a patient wearing said mask; a nosepiece integral with said mask, said nosepiece projecting outwardly from a wall of said mask, and adapted to extend over a nose of a patient wearing said mask; an exhalation valve (17) located adjacent said nosepiece, said exhalation valve adapted for positioning adjacent the nostrils of the nose, said exhalation valve comprising a one-way valve to permit air flow out of said mask upon exhalation, and to prevent air from entering into said mask upon patient inhalation; and

wherein said mask is adapted to cover the mouth and nose of the patient and further wherein said exhalation valve is integral with said wall of said mask.

As to claim 40, the distance of recession of the exhalation valve (17) within the tunnel-like extension illustrated in fig.1 of Braecklein is at least a diameter of the exhalation valve.

As to claim 41, the tunnel-like extension illustrated in fig.1 of Braecklein which houses exhalation valve (17) extends substantially to an end of said mask adjacent inlet (13).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 34,37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braecklein in view of Benos ('964).

The difference between Braecklein and claim 34 is the exhalation valve comprising a duckbill valve.

Benos teaches an exhalation valve (25) comprising an exhalation valve comprising a duckbill valve for the purpose of providing a means for exhaling without restraint (page 1, col.2, lines 45-53).

It would have been obvious to modify the exhalation valve of Braecklein to employ a duckbill valve as mere obvious substitution of one well known type of exhalation valve

for another. The duckbill valve of Benos would have provided a valve which is easily removed for cleaning and replacing.

Claim 37 is substantially equivalent in scope to claim 34 and is included in Braecklein as modified by Benos for the reasons set forth above with respect to claim 34.

5. Claims 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braecklein in view of Blount ('659).

The difference between Braecklein and claim 35 is a translucent mask.

Blount (col.1, lines 19-21 and col.2, lines 1-4) teaches a translucent or transparent mask (1) for the purpose of permitting observation of a patient's nose and mouth while using the mask.

It would have been obvious to modify the material of the mask of Braecklein to employ a translucent or transparent material because it would have permitted viewing of a wearer's nose and mouth during use as taught by Blount.

6. Claims 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braecklein in view of Benos as applied to claims 34,37 above, and further in view of Blount.

The difference between Braecklein as modified by Benos and claim 39 is a translucent mask.

Blount (col.1, lines 19-21 and col.2, lines 1-4) teaches a translucent or transparent mask (1) for the purpose of permitting observation of a patient's nose and mouth while using the mask.

It would have been obvious to further modify the material of the mask of Braecklein to employ a translucent or transparent material because it would have permitted viewing of a wearer's nose and mouth during use as taught by Blount.

### ***Claim Rejections - 35 USC § 112***

7. Regarding claims 33,38-40,42-46, the suffix "-like" in the recited term "...tunnel-like..." renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "-like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). One way of overcoming this rejection would be to use the phrase –tunnel shaped–.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 42-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No.

5,988,160. Although the conflicting claims are not identical (all elements of claim 42 are found in patent claim 1-13: an inlet (col.6, lines 21-25); a nosepiece (col.6, line 30); an

exhalation valve (col.6, line 40); a tunnel-like extension of instant application claim 38 (col.6, line 47); first and second frustoconical portions (col.6, lines 27 and 28, respectively), they are not patentably distinct from each other because the difference between claim 42 and patent claim 1 lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 is in effect a "species" of the "generic" invention of claim 42. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 42 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1.

Claim 43 recites an aerosol inlet which is found in patent claim 2 at (col.6, lines 21-25); the mask comprised of a first and second frustoconical taper which is found in patent claim 2 at (col.6, lines 27 and 28, respectively); a one-way valve recessed in a tunnel-like extension which is found in patent claim 2 at (col.6, lines 40-48).

The difference between claim 43 and patent claim 2 lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 2 is in effect a "species" of the "generic" invention of claim 43. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 43 is anticipated by claim 2 of the patent, it is not patentably distinct from claim 2.

### ***Response to Arguments***

10. Applicant's arguments filed 06/29/2004 have been fully considered but they are not persuasive. Applicant's arguments are grounded in the contention that the terms



"...integrally formed..." in claim 31 and "...integral with..." in claim 36 define structure which distinguishes over Braecklein. The terminology "...integrally formed..." includes the word "formed" which taken together define the manner of making of the mask and valve and as such applicant is reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. While the mask and exhalation valve of Braecklein may have been formed by a different process, it does include the claimed elements of the mask as defined in claim 31 and therefore, anticipates the mask of claim 31.

Further, a review of a standard dictionary definition of the word "integral" reveals that at least one of its meanings is "constituent" and in Braecklein the valves and mask constitute constituents of the whole device. Applicant's arguments regarding the multi-element valves of Braecklein are not persuasive because the valves including their elements constitute constituents of the whole device.

Applicant's assertion that the propriety of the combination of Braecklein and Benos is not valid due to an alleged lack of teaching or suggestion to combine is disagreed with. The prior art combination is valid for the reasons set forth above in the body of the rejection (i.e. the use of a duckbill valve because it provides for exhalation without the patient having to overly exert). One of ordinary skill would recognize the importance of

providing valves in Braecklein which enable a patient to inhale and exhale with ease while being treated with inhalable medicament.

Applicant's assertion that Braecklein fails to disclose a tunnel-like extension is not accurate because valve 17 in fig. 1 of Braecklein is illustrated as being situated within a space that is readable as "tunnel-like" inasmuch as it displays some of the physical characteristics of a tunnel (i.e. a three dimensional space with length being its largest dimension and being covered on all sides except one).

Applicant's arguments regarding the term "...tunnel-like..." are noted; however, the terminology is indefinite as to exactly what applicant intends to define given the hyphenated expression.

### ***Conclusion***

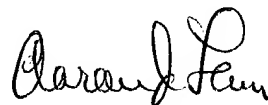
11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
October 02, 2004